

Remarks

Claims 12-45 and 48-64 have been canceled without prejudice or disclaimer, and the specification has been amended to correct the reference to a trademark as requested by the Examiner. No new matter has been added.

Claims 1-11 will be pending upon entry of this amendment.

I. Objection to the Specification

The Examiner has objected to the use of the trademark REDIPRIME™ in paragraph 0194, asserting that the usage was improper for lacking capitalization. In response, Applicants have amended paragraph 0194 in order to capitalize the mark. No further amendments to the specification are believed to be necessary.

II. Rejections Under 35 U.S.C. § 112, First Paragraph

A. Deposit Requirements

The Examiner has maintained the rejection of claims 12-22, 34-44 and 54-62 under 35 U.S.C. §112, first paragraph, alleging that the deposited material is not properly identified in the specification. In response, although Applicants disagree and maintain that the deposit was properly identified, claims 12-22, 34-44 and 55-62 have been canceled without prejudice or disclaimer, thereby obviating any rejection thereof.

B. Written Description

The Examiner has maintained the rejection of claims 23-45 and 48-62 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with written description requirement. In response, although Applicants disagree and maintain that the previously pending claims were in compliance with the written description requirement, claims 23-45 and 48-62 have been canceled without prejudice or disclaimer, thereby obviating any rejection thereof.

C. Enablement

The Examiner has maintained the rejection of claims 1-45 and 48-64 under 35 U.S.C. §112, first paragraph, alleging that the specification “does not reasonably provide enablement for making or using a full-length human (or murine) NKX3.1 protein of SEQ ID NO:2 or 4 or a full length NKX3.1 protein encoded by genomic DNA or cDNA of ATCC Deposit No. 209005 and 209006 or proteins having at least 95% identity with the protein of SEQ ID NO:2 or 4 or

peptides comprising 30 or 50 contiguous [sic] amino acids of SEQ ID NO:2 or 4." The Examiner alleges, *inter alia*, that: (1) the "specification is not enabling for expressing a recombinant full length NKX3.1 protein from a host cell"; and (2) the "specification is not enabling for showing a correlation between NKX3.1 mRNA and protein expression *in vitro* or *in vivo*."

Preliminarily, although Applicants disagree and maintain that the previously pending claims were in compliance with the enablement requirement, claims 12-45 and 48-64 have been canceled without prejudice or disclaimer, thereby obviating any rejection thereof. With respect to the rejection of claims 1-11, Applicants respectfully disagree and traverse as noted in the response of March 20, 2007 and as noted below.

The Examiner asserts that expressing the protein encoded by SEQ ID NOS:2 and 4 is not enabled, and appears to contend that for such a claim to be enabled, an *in vitro* model correlating the function of the claimed protein to "a biologically relevant transcription regulatory property" must be shown. Applicants respectfully disagree. As amended, the claims are narrowly drawn to the protein encoded by SEQ ID NOS:2 and 4. The evidence of record shows that NKX3.1 proteins have been expressed and used in the art, including for use in biological assays. *See, e.g.*, Steadman et al. (Ref. A97). The Examiner has not shown how the expression of the claimed protein and use in such assays, as set forth in the specification, is not enabled as of the filing date or would require undue experimentation. Applicants need only enable one use of the claimed invention (*see, e.g.*, MPEP §2164.01(c)), and to the extent that the Examiner is contending the claimed proteins must be themselves useful as a diagnostic or therapeutic agent, Applicants strongly disagree. Accordingly, Applicants respectfully assert that claims 1-11 are fully enabled, and request that the instant rejection as to such claims be reconsidered and withdrawn.

III. Rejection Under 35 U.S.C. § 102

The Examiner has rejected claim 64 under 35 U.S.C. § 102 as allegedly being anticipated by Sciavolino et al. and Bieberich et al. In response, while Applicants respectfully note that an antedating declaration was filed, claim 64 has been canceled without prejudice or disclaimer, thereby obviating the instant rejection.

IV. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 23-45 and 48-62 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. In response, while Applicants disagree, claims 23-45 and 48-62 have been canceled without prejudice or disclaimer, thereby obviating the instant rejection.

Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: November 23, 2007

Respectfully submitted,



Mark J. Hyman
Registration No.: 46,789
HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
14200 Shady Grove Road
Rockville, Maryland 20850
(240) 314-1224

MJH/ba